19-CV-977-J

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,

Plaintiff,

v.

GLEN MULREADY, in his official capacity as Insurance Commissioner of Oklahoma, and

OKLAHOMA INSURANCE DEPARTMENT,

Defendants.

DEFENDANTS' REPLY IN SUPPORT OF SUMMARY JUDGMENT

I. There is no disputed, material fact that would preclude summary judgment.

In response to Defendants' motion for summary judgment, PCMA admits 24 out of 31 of Defendants' facts. Doc. 98 at 2-7 (declining to dispute Paragraphs 1-7, 9-10, 12, 15-21, 23-25, 27-29, and 31). But even the facts PCMA claims to dispute aren't really disputed. Rather, PCMA merely attempts to contextualize them in some non-substantial way:

8. PCMA claims this fact is disputed, even though it is based entirely on statements made by PCMA's own expert about the general need for PBM oversight. Oddly, PCMA also claims that this fact—again, based solely on its expert's testimony—"merely echoes the reasons independent pharmacies advocated in support of the Act." PCMA offers no citation to evidence to support its claim that this fact is disputed. *See* Local Rule 56.1(c)-(e). Instead, it cites to a different portion of the expert's testimony where he provides additional thoughts on oversight. He does not retract or narrow his previous statements, nor does he actually say the "market" provides adequate oversight, as PCMA claims. *See* Doc. 97-10 at 172-73.

11. PCMA claims this fact is disputed, even though (again) one of the underlying sources is PCMA's own expert, who acknowledged that people use the phrase "take-it-or-leave-it" to describe pharmacy/PBM negotiations and said "it's pretty much not a flexible scenario." Doc. 96-6 at 79-82. PCMA's only cited evidence for a "dispute" is the testimony of Defendants' expert that independent pharmacies in Oklahoma are represented by an organization that assists with contract negotiation. *See* Doc. 98-1 at 29. This does not dispute Defendants' stated fact that independent pharmacies have little to no bargaining power.

13. PCMA does not dispute that this is an accurate representation of what the White House Council of Economic Advisors wrote about PBM market power "against" health plans and "outsized" PBM profits, which is all that Defendants had stated in the first place.

14. PCMA admits in response to this fact that "pharmacies are sometimes reimbursed below cost," which is nearly indistinguishable from Defendants' stated fact itself. The only quibble appears to be whether "often," "sometimes," or "small percentage," is the appropriate term to use. The distinction between these terms is largely in the eye of the beholder, and not material to the undisputed underlying point that such underwater reimbursements are happening.

22. PCMA offers nothing to directly dispute this fact. Rather, PCMA claims only that it is the health plans, not the PBMs, that make the ultimate determinations about networks and pharmacies. But this ignores our citation to PCMA's own expert, who admitted that it is the PBMs, and not health plans, who are doing the gate-keeping for preferred pharmacy networks and the health plans and their consultants are not seeing the details of whether specific pharmacies are allowed to participate or not. *See* Doc. 96-7 at 110-11.

26. PCMA disputes this fact only "to the extent it implies PBMS are the cause of rising drug prices." In other words, this is not actually disputed. Indeed, Defendants even included a citation pointing out that PCMA blames the drug manufacturers for the rising drug prices. *See* Doc. 96-5 at PCMA0000154, 312.

30. Finally, there is no tension between this Court's general description of OKLA. STAT. tit. 36, § 6963(E) in its denial of a preliminary injunction and the Oklahoma Attorney General's letter addressing a specific question about that provision regarding preferred

pharmacy networks. This Court simply did not address the same question in the Order as the Attorney General did in the letter. *Compare* Doc. 48 at 2-3, *with* Doc. 97-12.

II. PCMA's blanket immateriality claim undermines its own theory of the case.

PCMA claims that "almost all" of Defendants' facts are immaterial. Doc. 98 at 1. In a vacuum, that might be correct, as the questions about ERISA and Medicare Part D preemption raised in this case are assuredly questions of law suitable for summary judgment. But PCMA has argued and is still arguing that "interfering with PBM pharmacy and beneficiary relationships is essentially the same as interfering with the plan's pharmacy and beneficiary relationships and, therefore, the plan's benefit designs." Doc. 97-1 at 12. In other words, the core of PCMA's argument concerns the relationship between PBMs and health plans. Indeed, PCMA even insists at one point in its response that this Court *must* consider that relationship. *See* Doc. 98 at 27 (arguing that PCMA's federal and state claims "*require* the court to consider the relationship between health plans, health insurers, and PBMs" (emphasis added)). In short, PCMA contends that PBMs and health plans are inseparable for purposes of preemption analysis, and that when the Pharmacy Choice Act regulates PBMs it is actually and inappropriately regulating health plans. But at the same time, in response to Defendants' undisputed facts concerning the actual PBM/health plan relationship, PCMA claims total immateriality. PCMA cannot have it both ways. PCMA has made its argument, and Defendants have responded with undisputed facts material to that argument.

At bottom, nothing special about the contractual relationship between PBMs and health plans transforms the PBM into a health plan any more than any other contractual relationship does so in any other circumstance. While PCMA points out that health plans must

sign off on the final contract, their argument ignores that the contract is the result of an arms-length negotiation with the same give-and-take and back-and-forth of standard contractual negotiations. PCMA's argument is rebutted by, among other things, the undisputed fact that no law requires health plans to contract with PBMs (Defs' Fact #3), the undisputed fact that PBMs are not fiduciaries to health plans (Fact #4), the undisputed fact that contracts between PBMs and health plans are the result of arms-length negotiations (Fact #5), the undisputed fact that PBMs have their own profit motive underlying their actions (Fact #6), the undisputed fact that health plans are aware of this separate profit motive (Fact #7) and thus believe PBMs need oversight (Fact #8), and the undisputed fact that PBMs attempt to incentivize health plans through standard negotiations to let PBMs self-deal in their relationships with pharmacies (Fact #17). To be sure, however, if PCMA's theory of the case is rejected—as it should be—then these facts would become immaterial.

Many of the other undisputed facts PCMA blithely dismisses as "merely echo[ing] the reasons independent pharmacies advocated in support of the Act." While these facts do show why support for the Act was so broad and unanimous, they also go to show the questionable and controversial actions embraced by PBMs that the Pharmacy Choice Act is addressing. These facts provide important background for the Act and show that the Act is not aimed at health plans but rather at PBMs. After all, it was not the acts of employee health plans that prompted the legislation here or similar legislation nationwide. It was the acts of PBMs. In other words, these facts serve much of the same purpose as the facts listed above—they rebut PCMA's claims that health plans are being targeted and regulated here, rather than PBMs.

Similarly, PCMA relies on the principles of economics as grounds for its argument that PBMs and health plans are essentially one and the same. *See* Doc. 98 at 2, RDF3 (quoting *PCMA v. District of Columbia*, 613 F.3d 179, 188 (D.C. Cir. 2010)). In such a highly regulated field (with the exception of PBMs), reliance on economic theory for this proposition is dubious at best. *Cf.* Doc. 96 at 3, No. 13 (White House Council of Economic Advisors: PBMs are exercising "undue market power … against health plans"). But in any case, the Supreme Court has expressly rejected the theory that state laws that have no more than an "indirect economic influence" on plan choices can be said to be "a regulation of an ERISA plan itself." *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 659 (1995). Economics is all about incentives—that is, the invisible (and indirect) hand of the market. No doubt these state laws are "alter[ing] the incentives" facing ERISA plans, but they are "not dictat[ing] the choices." *Calif. Div. of Lab. Standards Enf't v. Dillingham*, 519 U.S. 316, 334 (1997).

To hold that indirect economic influence triggers preemption under ERISA would be to declare that PBMs are unable to be regulated at all, given that virtually everything they do at least indirectly affects health plans' economic incentives in some way.

III. PCMA's overbroad preemption theories should be rejected.

In the end, PCMA seeks to return to the overbroad, unhelpful ERISA preemption analysis that the Supreme Court has rejected, and then also apply a similarly overbroad framework to Medicare Part D preemption analysis. In no way did *Rutledge v. PCMA* preserve ERISA preemption for the provisions at issue here. *See* 141 S. Ct. 474 (2020). Quite the opposite, in addition to the regulation on MAC pricing, *Rutledge* also approved of Arkansas's decline-to-dispense provision—even though, as applied to ERISA plans, that provision

authorized pharmacies to decline to provide an ERISA benefit to ERISA-covered beneficiaries. That provision regulated the relationship between two service providers: PBMs and pharmacies. *Rutledge*, 141 S. Ct. at 482. According to the Supreme Court, it did not regulate health plans and did "not require plans to provide any particular benefit to any particular beneficiary in any particular way." *Id.* Under PCMA's theory of benefit design, Arkansas's provision should have been preempted. But it wasn't. And neither should be the provisions of the Pharmacy Choice Act at issue here.

In fact, *Rutledge* reiterated the approach taken in *Travelers* and *Dillingham*. That is, the Supreme Court declined to stretch ERISA's preemptive effect beyond its existing domain to state laws "quite remote from the areas with which ERISA is expressly concerned—'reporting, disclosure, fiduciary responsibility, and the like.'" *Dillingham*, 519 U.S. at 330 (citations and quotations omitted). Indeed, under *Dillingham*, "ERISA [is not] concerned with any state action … that … potentially affect[s] the choices made by ERISA plans." *Id.* at 329. In a self-serving manner, PCMA merely wants a return to the rejected standard that if "taken to extend to the furthest stretch of its indeterminacy, then for all practical purposes pre-emption would never run its course." *Travelers*, 514 U.S. at 655. That approach should be rejected again here.

But PCMA does not stop there. It seeks to take that indeterminate standard and apply it to Medicare Part D analysis. PCMA asks this Court to reject the "overlapping" standard requirement that every court to address the issue has adopted in favor of an amorphous test that requires preemption of anything remotely connected to the subject matter at issue in a Medicare Part D standard. PCMA's approach, if accepted, would include anything on the same subject matter regardless of how, who, what, or why. And, like PCMA's ERISA preemption

theory, it's hard to see where the limits of preemption end or if they do at all. With subsequent support of the courts, the Centers for Medicare and Medicaid Services (CMS) has long ago rejected PCMA's approach, saying that "although the Congress included broad preemption rules . . . we d[o] not believe that the Congress intended for each and every State requirement applying to [Part D plans] to become null and void." CMS, *Medicare Program; Medicare Prescription Drug Benefit*, 70 Fed. Reg. 4,194, 4,319 (Jan. 28, 2005). CMS's approach is reasonable and leaves adequate room for preemption—and indeed the State has demonstrated a willingness to abide by all Medicare Part D standards that preempt state law. But PCMA's expanded view of preemption under Medicare Part D should be rejected.

* * *

The issues here have now been briefed multiple times, and were argued by counsel at the preliminary injunction stage. They have not materially changed since then. The only intervening occurrence was that this Court's analysis was confirmed by a unanimous Supreme Court in *Rutledge*. Respectfully, at this point, Defendants believe further hearings or oral arguments would do little to aid in the decisional process.

CONCLUSION

Except as provided herein, judgment should not be entered for Plaintiff.

Respectfully submitted,

s/ *Randall Yates*

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